



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: DEX-0207
Inventors: Macina et al.
Serial No.: 09/867,034
Filing Date: May 29, 2001
Examiner: Davis, Natalie, A.
Group Art Unit: 1642
Title: Method of Diagnosing, Monitoring,
Staging, Imaging and Treating Colon
Cancer

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By Kathleen A. Tyrrell
Typed Name: Kathleen A. Tyrrell

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Reply to Restriction Requirement

This is a reply to the Restriction Requirement dated
January 23, 2002 setting a one (1) month statutory period for
response. Please enter the following remarks into the record.

REMARKS

Claims 1 through 14 are pending in the instant application.
Claims 1 through 14 has been subjected to a Restriction
Requirement as follows:

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Group I, claims 1(a) and (c) and 14, (as it reads on nucleic acids), drawn to a CSG polynucleotide and vaccine, classified in class 536, subclass 23.1;

Group II, claims 1(b) and 14 (as it reads on protein), drawn to a CSG protein and vaccine, classified in class 530, subclass 350;

Group III, claims 2-6, drawn to a method of diagnosing, staging and monitoring the presence and metastasis of colon cancer, classified in class 435, subclass 4;

Group IV, claim 7, drawn to a method of identifying potential therapeutic agents, classified in class 435, subclass 4;

Group V, claim 8, drawn to an antibody of claim 1, classified in class 530, subclass 387.9;

Group VI, claims 9-10, drawn to a method of imaging colon cancer, classified in class 424, subclass 1.49;

Group VII, claim 11, drawn to a method of treating colon cancer, classified in class 424, subclass 184.1; and

Group VIII, claims 12-13, drawn to a method of inducing an immune response, classified in class 514, subclass 2.

The Examiner suggests that these Groups are distinct inventions. Specifically, the Examiner suggests that the

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products of Groups I-II and V can be used with materially different processes than those of Groups III-IV and VI-VIII. In addition, with respect to Groups I, II and V, the Examiner suggests that the products are structurally and functionally different molecules with different immunological properties, modes of action, and half-life. With respect to Groups III-IV and VI-VIII, the Examiner suggests that they relate to methods with different steps, modes of operation, reagents needed and serve different endpoints and effects.

Applicants respectfully traverse this Restriction Requirement.

MPEP §803 provides two criteria which must be met for a restriction requirement to be proper. The first is that the inventions be independent or distinct. The second is that there would be a serious burden on the Examiner if the restriction is not required. A proper search of the prior art relating to the Group I, should also reveal art relating to the claims of Groups II through VIII. Thus, it does not appear that a serious burden would be placed upon the Examiner if restriction were not made.

Accordingly, since this Restriction Requirement does not meet both criteria as set forth in MPEP § 803 to be proper, it is respectfully requested that this Restriction Requirement be

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withdrawn.

However, in an earnest effort to be completely responsive, Applicants elect to prosecute Group I, claims 1(a) and (c) and 14, with traverse.

The Examiner has also suggested that a species election is required with respect to Groups I and II. Specifically, the Examiner suggests that applicant is required to elect a single species of CSG comprising either species A through V, drawn to SEQ ID NO: 1 through 22, respectively. The Examiner suggests that Species L-V are patentably distinct based on structural and functional differences.

Applicants respectfully disagree with this requirement.

In accordance with MPEP § 808.01, an election of species should be made when a generic claim recites such a multiplicity of species that an unduly extensive and burdensome search is required. In the instant case, however, the generic claim is not drawn to such a large multiplicity that search of all species would be unduly extensive or burdensome. Only 22 sequences have been set forth by the Examiner as different species. Accordingly, reconsideration of this species election requirement is respectfully requested.

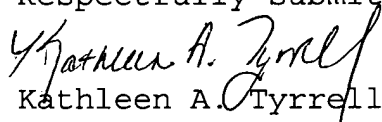
In an earnest effort to be completely responsive, however

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Applicants elect Species E (SEQ ID NO:5), with traverse.

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record.

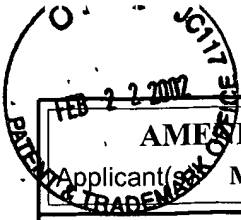
Respectfully submitted,


Kathleen A. Tyrrell
Reg. No. 38,350

Date: February 22, 2002

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02-25-02

GP/1642

AMENDMENT TRANSMITTAL LETTER (Large Entity)

Applicant(s) Macina et al.

Docket No.

DEX-0207

Serial No.

09/867,034

Filing Date

May 29, 2001

Examiner

Natalie A. Davis

Group Art Unit

1642

Invention: METHOD OF DIAGNOSING, MONITORING, STAGING, IMAGING AND TREATING
COLON CANCER

TO THE ASSISTANT COMMISSIONER FOR PATENTS:

Transmitted herewith is an amendment in the above-identified application.

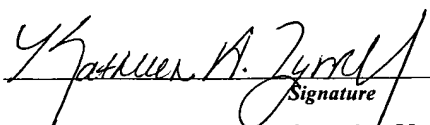
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CLAIMS AS AMENDED

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TOTAL CLAIMS	14 -	20 =	0 x	\$18.00	\$0.00
INDEP. CLAIMS	1 -	3 =	0 x	\$84.00	\$0.00
Multiple Dependent Claims (check if applicable) <input type="checkbox"/>					\$0.00
TOTAL ADDITIONAL FEE FOR THIS AMENDMENT					\$0.00

- ☒ No additional fee is required for amendment.
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A duplicate copy of this sheet is enclosed.
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- ☒ Any additional filing fees required under 37 C.F.R. 1.16.
- ☒ Any patent application processing fees under 37 CFR 1.17.


Signature

Dated: February 22, 2002

Kathleen A. Tyrrell, Registration No. 38, 350

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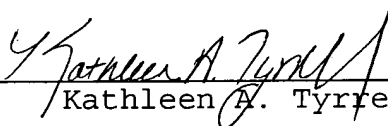
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- 1) Amendment Transmittal Letter (in duplicate);
- 2) Response to Restriction Requirement;
- 3) Return Postcard.


Kathleen A. Tyrrell